

REMARK

Reconsideration and withdrawal of the rejections set forth in the Office Action dated November 2, 2005 are respectfully requested. Claims 18-24, 28-35, and 47 are pending in the application.

I. Amendments

A. Claim Amendments

The pending claims are amended to include reference to a temperature at which the viscosity and solubility values are determined. Basis for the amendment is found, for example, in the Examples where drug coating solutions were prepared at room temperature. Basis is also found in paragraph [00032], where a technique for coating a microprojection described in a co-owned provisional patent application (serial no. 60/276,762) is incorporated by reference. In paragraph [00012] of the 60/276,272 application, the drug coating solution is described, and solubility and viscosity parameters of the coating solution are set forth. It is noted that the viscosity of the coating solution is measured at a temperature of 25°C.

For the Examiner's convenience, Applicants enclose a copy of the 60/276,272 application as filed with the U.S. PTO on March 16, 2001. In anticipation of compliance with M.P.E.P. § 608.01(p)(I)(A)(1), Applicants have amended the disclosure of the present application in paragraph [00014] to include the material that was incorporated by reference and now added to the claims. A Declaration signed by Applicants' representative stating that the amendatory material consists of the same material incorporated by reference is also enclosed.

Claim 21 is amended to specify that the coating is less "thick" than a thickness of the microprotrusions. Basis is found in paragraph [00015].

Claim 23 is amended to provide full names of the acronyms, with a parenthetical reference to the acronym. Basis is found in paragraphs [00021] and [00037].

Claim 29 is amended for internal consistency with respect to the amount administered.

Claims 36-46 and 48-50 are cancelled, without prejudice to Applicants rights to pursue the subject matter of these claims in a subsequently filed application.

B. Claim Amendments

The specification is amended, in compliance with 37 C.F.R. § 1.78(a)(4)-(a)(5)(i), to include a reference to the priority information set forth in the original application filing papers (see unsigned Combined Declaration and Power of Attorney submitted October 26, 2001). Because

the Office recognized Applicants' priority claim, as evidenced by its inclusion on the filing receipt, nothing more (such as a petition or surcharge) is required by Applicants to perfect the priority claim (M.P.E.P. § 201.11(V)).

The specification is also amended to correct typographical errors and to provide full names for the well-known acronyms in paragraphs [00021] and [00037].

II. Double-Patenting Rejection

Claims 18-24, 28-35, and 47 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claims 54-64 of copending application no. 11/034,891. This rejection is respectfully traversed for the following reasons.

According to the M.P.E.P. § 804, in determining whether a nonstatutory basis exists for a double-patenting rejection, the first question to be asked is – does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?". The question seeks to determine if the invention of the pending application is a mere variation (which would have been obvious to those of ordinary skill in the art) of an already claimed invention.

In the instant case, the pending claims relate to a method of making a device for transdermally delivering a pharmacologically active agent. The method, as set forth in exemplary claim 18, comprises (i) providing a member having a plurality of stratum corneum-piercing microprotrusions; (ii) applying an aqueous solution of the pharmacologically active agent onto the member; and (iii) drying the applied aqueous solution to form a dry agent-containing coating on the member. In the various embodiments of the invention set forth in the claims, the agent has, for example, a sufficient potency to permit administration of less than a certain amount, and an aqueous solubility of greater than a certain amount, and/or a viscosity less than a certain amount.

Claims 54-64 in co-owned, co-pending application serial no. 11/034,891 (hereinafter "the '891 application") relate to a method for transdermally delivering a biologically active agent by providing a device having skin-piercing microprojections, where the microprojections have (i) a dried formulation of a biologically active agent, (ii) a non-volatile counterion, and (iii) a volatile counterion. Claim 54 recites that the non-volatile counterion causes formation of a first species of the biologically active agent that has improved solubility and the volatile counterion causes formation of a second species of the biologically active agent that has reduced solubility when the formulation is dried.

Instant claims 18-24, 28-35, and 47 do not describe or suggest the features set forth in claim 54 of the '891 application of a non-volatile counterion and a volatile counterion. Nor do instant claims 18-24, 28-35, and 47 describe or suggest that the non-volatile counterion causes formation of a first species of the biologically active agent that has improved solubility and the volatile counterion causes formation of a second species of the biologically active agent that has reduced solubility when the formulation is dried.

Since these features are not shown or suggested in the pending claims, it cannot be said that the pending claims 18-24, 28-35, and 47 are a mere variation of the invention as claimed in the '891 application. Accordingly, withdrawal of the provisional rejection for obviousness-type double patenting is respectfully requested.

III. Rejections under 35 U.S.C. § 112, second paragraph

Claim 21, 23, and 29 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 21 was objected to as being confusing. Claim 21 is amended to specify that the coating is less "thick" than a thickness of the microprotrusions.

Claim 23 was objected to as being indefinite due to the abbreviations and the terms in parentheses and brackets. Claim 23 is amended to provide full names of the abbreviations with the abbreviation included as a parenthetical reference. With respect to the information in brackets, deamino [Val4, D-Arg8] arginine vasopressin, this terminology is common in the art to indicate the amino acid residues that have been modified from the parent compound. In the deamino [Val4, D-Arg8] arginine vasopressin, the amino acid residue at position 4 is a Val (rather than Gln in the parent compound arginine vasopressin) and the Arg residue at position 8 is D-Arg.

Claim 29 is amended for internal consistency.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

IV. Rejections under 35 U.S.C. § 102

Claims 1-15 and 20-21 were rejected under 35 U.S.C. §102(e) as being anticipated by Dalton, WO 02/07813. This rejection is respectfully traversed for the following reason.

The present application was filed on October 26 2001, with a priority claim to October 26, 2000.

Dalton has an international filing date of July 18, 2001.

According to the M.P.E.P. § 706.02(a), an international filing date which is on or after November 29, 2000 is a U.S. filing date if the international application designated the U.S. and was published in the English language. The front page of the Dalton PCT publication indicates that the U.S. is a designated state. The Dalton publication is in the English language. Therefore, the prior art reference date of Dalton under 35 U.S.C. § 102(e) is the international filing date of July 18, 2001.

The filing date of the foreign application on which the Dalton application is based (GB 0017999.4) may not be used as a 35 U.S.C. § 102(e) date for prior art purposes (M.P.E.P. § 706.02(f)(1)(I)(D)).

Accordingly, since the present application is entitled to the benefit of the provisional application filed October 26, 2000 and since Dalton has a 35 U.S.C. § 102(e) date of July 18, 2001, Dalton does not qualify as prior art under § 102(e).

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102.

V. Rejections under 35 U.S.C. § 103(a)

Claims 22-24 and 34-35 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Dalton. This rejection is respectfully traversed on the grounds that Dalton does not qualify under any subsection of 35 U.S.C. §102 as prior art, as discussed in the section above. Accordingly, withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

VI. Conclusion

In view of the above amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Therefore, a Notice of Allowance is respectfully requested. If the Examiner believes a telephone conference would expedite the prosecution of the present application, the Examiner is encouraged to call the undersigned at (650) 564-5887.

Respectfully submitted,

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